

REMARKS/ARGUMENTS

The claims are divided into the following Groups:

Group I: Claim(s) 1-12, drawn to a pharmaceutical formulation.

Group II: Claim(s) 17, drawn to a pharmaceutical formulation.

Applicants elect, with traverse, Group I, Claims 1-12, for examination.

Restriction is only proper if the claims of the restricted groups are independent or patentably distinct and there would be a serious burden placed on the Examiner if restriction is not required (MPEP §803). The burden is on the Examiner to provide reasons and/or examples to support any conclusion in regard to patentable distinction (MPEP §803). Moreover, when citing lack of unity of invention in a national stage application, the Examiner has the burden of explaining why each group lacks unity with each other group specifically describing special technical features in each group (MPEP § 1893.03(d)).

The Office has asserted that Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1, because under PCT Rule 13.2, they lack the same or corresponding special technical features. The Office alleges that Group II does not recite all the limitations of Group I and therefore does not share the special technical features of Group I.

Applicants respectfully note that the claims 1-12 have been previously examined and that the newly added claim does not add subject matter which has not been examined. The MPEP § 811 states:

“Before making a restriction requirement after the first action on the merits, the examiner will consider whether there will be a serious burden if restriction is not required.”

Applicants respectfully submit that since Claims 1-12 have already been searched and examined, a serious burden is not created by the new claim. The Office, in its own definition of

the Groups, has indicated that both groups are pharmaceutical formulations. (Office Communication dated January 8, 2009, page 2, lines 15-16)

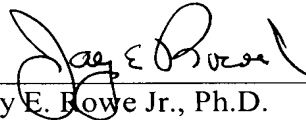
Accordingly, and for the reasons presented above, Applicants submit that the Office has failed to meet the burden necessary in order to sustain the requirement for restriction.

Applicants therefore request that the requirement for restriction be withdrawn.

Applicants respectfully submit that the above-identified application is now in condition for examination on the merits, and early notice thereof is earnestly solicited.

Respectfully Submitted,

OBLON, SPIVAK, McCLELLAND,  
MAIER & NEUSTADT, P.C.  
Norman F. Oblon



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Jay E. Rowe Jr., Ph.D.  
Registration No. 58,948

Customer Number

**22850**

Tel. (703) 413-3000  
Fax. (703) 413-2220  
(OSMMN 08/07)